Remarks

Reconsideration is respectfully requested. Claims 1-3 and 6-23 were pending. Claims 8-20 are withdrawn. Claims 1 and 22 are amended to present the claims in better form for consideration on appeal. Claims 21 and 23 are canceled. Upon entry of this amendment, claims 1-3, 6-20 and 22 will be pending.

No new matter is introduced by this amendment.

Rejections Under 35 U.S.C. § 103(a)

Claims 1-3, 6, 7, and 21-23 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over International Application No. WO 01/93847 to Kern and Heisey (Kern) in view of The Ultimate Southern Living Cookbook by Gunter, 1999 (Gunter). The Examiner alleges it would have been obvious to combine the glaze composition disclosed in Kern with the methods for preparing glazes disclosed in Gunter. Applicants disagree and traverse.

Kern discloses compositions including a chondroprotective agent (*e.g.*, glucosamine, N-acetylglucosamine). In Example 14, Kern discloses a glaze composition that includes, among other ingredients, glucosamine. Kern does not teach or suggest heat-processing the glaze or combining it with a baked component.

Gunter discloses recipes for glazes and fillings wherein the glaze or filling is heated over medium heat during preparation, and discloses that glazes can be drizzled over a cake, *i.e.*, a baked component. Gunter does not teach or suggest adding NAG, glucosamine, or any food supplement to a glaze or filling.

Claims 1-3, 6 and 7

Amended claim 1 recites a food composition comprising at least one baked component and at least one heat-processed component comprising a cartilage supplement, "wherein *the heat-processed component comprising the cartilage supplement was heated at a temperature from about 160°F to about 180°F*, and contains at least 70% of an initial concentration of the cartilage supplement after heat processing." (Emphases added.)

The Examiner alleges that the limitations following "wherein" are directed to a product-by-process, and that "product-by-process claims are not limited to the manipulations of the recited steps, they are only related to the structure." (Office action, ¶ 5.) Applicants respectfully disagree.

In support of the rejection, the Examiner cites *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (MPEP § 2113), which states, "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." (Office action, ¶ 5.)

The Federal Circuit stated in the *Abbott Laboratories v. Sandoz, Inc.* decision on May 18, 2009, "More recently the Supreme Court has reiterated the broad principle that '[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention'...As applied to product-by-process claims, Warner Jenkinson thus reinforces the basic rule that the *process terms limit product-by-process claims*." *Abbott Laboratories v. Sandoz, Inc.*, --- F.3d ----, , 2009 WL 1371410, Fed.Cir.(Ill.), May 18, 2009 (NO. 2007-1400, 2007-

1446), (Page 18 of the attached copy.) (emphasis added). Accordingly, *claim 1 is limited by the process term* requiring that the cartilage supplement be present while the heat-processed component is heated at a temperature from about 160°F to about 180°F. This feature is neither taught nor suggested by either Kern or Gunter.

The Examiner further alleges that one of ordinary skill in the art could add the GLCN and/or NAG to a heat-processed component such as Gunter's glaze after heating, and after the component had cooled to a temperature amenable to GLCN and/or NAG addition. The resultant compound would be indistinguishable from the product-by-process recited in claim 1. (Office action, ¶ 5.) However, such a modification necessarily relies upon impermissible hindsight. There is no indication in either Kern or Gunter that temperature plays a role in the stability of GLCN and/or NAG. Also, there is no teaching or suggestion whatsoever in either Kern or Gunter to heat the glaze first over medium heat *and then subsequently cool the glaze to 160-180°F before adding the GLCN and/or NAG.* Thus, a person of ordinary skill in the art would have no motivation to modify Gunter's process as suggested by the Examiner. Furthermore, claim 1 explicitly requires that the cartilage supplement is present in the heat-processed component during the heating step.

As discussed above, because neither Kern nor Gunter recognizes the importance of controlling the heat to which GLCN is subjected, it would not have been obvious from the combination of Kern and Gunter to add the glucosamine after heating and then partially cooling the glaze. Instead, a person of ordinary skill in the art would add the glucosamine to the glaze composition prior to heating at medium heat. Subsequently, the heating step disclosed by Gunter would significantly degrade the glucosamine, as previously discussed in the Response submitted February 25, 2009. Rather than being indistinguishable from the product-by-process recited in

claim 1, the resulting heat-processed component would differ significantly from the heat-processed component recited in claim 1 of the instant application, which contains at least 70% of an initial concentration of the cartilage supplement *after* heat processing. Additionally, when GLCN is exposed to temperatures exceeding the claimed range of about 160°F to about 180°F, the resulting food product often times has one or more undesirable characteristics, such as an unpleasant taste or undesirable browning. During taste tests of products comprising GLCN, such as bread baked at high temperatures, participants described the product as having an earthy, bitter, burnt, or vinegar taste. (Specification, page 8, ll. 11-15, and Example 1, pp. 14-15.) Thus, even under *In re Thorpe* as cited by the Examiner, the process term affects the patentability of the product because the product is not the same as or obvious from a product of the prior art. Accordingly, the process term properly limits the product-by-process claim, and claim 1 is allowable over the combination of Kern and Gunter.

Claims 2, 3, 6 and 7 depend from claim 1 and are allowable for at least the same reasons as claim 1, as well as based on each claim's unique and non-obvious combination of features. For example, claim 3 recites that the heat-processed component is at a pH of at least 9. The Examiner states that, "There is no mention of a pH requirement for the stability of the GLCN in the foodstuffs disclosed in Kern and Heisey. Therefore, the arguments [in the 2/25/09 response] are seen to be irrelevant to the basis of rejection under 35 USC 103(a)." (Office action, ¶ 6.) Applicants respectfully disagree.

Kern discloses compositions having a first component comprising a chondroprotective agent (*i.e.*, GLCN) and a second component comprising a cation source and an edible acid source." Kern explicitly states that, "The present inventors have surprisingly discovered that addition of an acidic second component to the chondroprotective agent...maintains the stability

of such agent. Indeed...the presently described *acidic compatible matrix optimizes the stability of the chondroprotective agent, e.g., glucosamine.*" (Kern, page 2, ¶ 2, emphasis added.) An acidic matrix inherently has a pH of less than 7. Thus, Kern clearly has a pH requirement for the stability of the GLCN (*i.e.*, the first component) in the disclosed foodstuffs. Based upon Kern's teaching that an acidic environment stabilizes the cartilage supplement, a person of ordinary skill in the art would not be motivated to prepare a heat-processed component comprising a cartilage supplement at a pH of at least 9. In particular, one would not reasonably expect the heat-processed component with a pH of at least 9 to contain at least 70% of the initial concentration of cartilage supplement after heat processing.

Claims 21-23

Claims 21 and 23 are canceled. Claim 22 recites a food composition comprising "at least one heat-processed component comprising glucosamine, wherein the heat-processed component comprising glucosamine does not require pH adjustment, was heated at a temperature of about 160°F to about 180°F, and contains at least 70% of an initial concentration of glucosamine after heat processing." As discussed above in relation to claim 1, the Federal Circuit has recently clarified in *Abbott Laboratories v. Sandoz, Inc.* that process terms do limit product-by-process claims. Therefore, the heat processing temperature limitation is relevant to the consideration of patentability. The temperatures taught by Gunter exceed the claimed temperature range of about 160°F to about 180°F. Additionally, the combination of Kern with Gunter would degrade the glucosamine in Kern's glaze due to the excessive heat taught by Gunter, resulting in a product that is significantly different than the product recited in claim 22. Thus, the process term is also relevant under *In re Thorpe*, as cited by the Examiner. Accordingly, claim 22 is allowable over

the combination of Kern and Gunter.

The claims in their present form are allowable. Such action is respectfully requested. The Examiner is invited to contact the undersigned at the telephone number listed below if such a call would facilitate allowance of this application.

Respectfully submitted,

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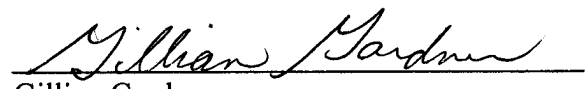
By 
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